REMARKS

Claims 1, 3-5, and 16-29 are presently pending for the Examiner's review and consideration, and claims 6-15 have been withdrawn from consideration, but depend from claim 1, which is being examined. Claims 1, 3-6, 12, and 16-23 are presently amended, and new claims 26-29 are added.

The amendments and new claims are fully supported in the originally filed specification, claims, and drawings. For example, claim 26 is supported in the first paragraph on page 9, claim 27-29 are supported in the first paragraph on page 7 and in the figures. New claims 26-29 are directed to the elected species.

The amendments to the claims are made under 35 U.S.C. § 112, second paragraph to more particularly define the invention. For example, claim 20 has been amended to more clearly define the meaning of an average length to diameter ratio, in that it must include a measurement of an average diameter along the length over which the ratio is taken. This is fully supported in the application, as explained for example in the Sund Declaration ¶ 6. Claim 1 has a similar amendment. Claim 16 has been amended to clarify that the diameter is constant over the channel portion over which the ratio is measured. These claims have also been amended to clarify that the portion of the discharge channel over which the ratio is measured is the portion that ends in the orifice.

Claims 1, 3-5, 16-17, 20-22, 24, and 25 were rejected under 35 U.S.C. § 102(e) as anticipated by Lilley. Also, claims 18, 19, and 23 were rejected under 35 U.S.C. § 103(a) as obvious over Lilley.

Claim 1 defines an injection device with a discharge channel that includes a channel portion that terminates in an orifice. The channel portion and has a length to average diameter ratio of greater than 6/1. Claim 16 defines that the channel portion that ends at an orifice that has the same diameter as the channel portion over the length of the channel portion, and claim 20 also defines that the channel portion ends at an orifice and that the ratio is of the length to the average diameter of the channel portion. Each of these claims also defines a fluid chamber with the other end of the channel is in fluid communication. Also, claim 21 further defines that the channel diameter is substantially equal to the orifice diameter adjacent thereto, which is where the ratio is measured, and claim 22 further defines that the channel has a constant diameter where the ratio is measured.

The argumentation in support of the rejection in the Office Action explains that the ratios defined in the claims were being measured taking the entire length of the nozzle assembly 20A or 20B shown in Figs. 10 and 11 of the Lilley patent, which the Office

action refers to as a "probe," but taking only the diameter at the tip of the orifice 24. It is noted that the Office Action included drawings attached at the back that show a line dividing the portion of the nozzle assemblies 20A,20B ahead of the plungers 30A,30B in Figs. 10 and 11 of the Lilley patent.

As explained in Mr. Sund's Declaration Under 37 C.F.R. § 1.132, it is not proper to measure the ratio as done in the Office Action. The independent claims define the channel portion over which the ratio is measured, and state that this portion is in fluid communication with a fluid chamber. Instead, the Examiner included the length of the fluid chamber and possibly more looking at Lilley for purposes of the rejection. Mr. Sund also declares that it is improper to measurement of an average diameter to only include the diameter at the tip of the Lilley orifice. (Sund Declaration, ¶¶ 3-7.)

With respect to the Office Action's inclusion of the Lilley ampule in the length measurement for the ratio, claim 27 recites that a the fluid chamber is significantly larger in cross-sectional area than the channel portion, claim 28 recites that the nozzle assembly has a tapered portion between the fluid chamber and the discharge channel, and claim 29 recites that the tapered portion is configured to accommodate the plunger. These features are present behind the portion of the channel over which the ratio is measured. In Mr. Sund's opinion, one of ordinary skill in the art would further interpret these claims as requiring a much shorter length measurement for the claimed ratio than used by the Examiner.

The Sund declaration evinces that the claimed ratios are neither inherent, taught, or obvious in view of Lilley. In the Lilley patent, there is no length that can be measured over which the average diameter is sufficiently small so that the length to average diameter ratio will be at least 6/1, as recited in claims 1 and 20. Similarly, there is no potion of a discharge channel in the Lilley patent that has the same diameter as the orifice and has at least a length to diameter ratio of 6/1, as recited in claims 16, 21, or 22. (Sund Declaration, ¶ 9.) Mr. Sund further explains that there would be no suggestion to modify Lilley to include the elevated claimed ratios because, (1) it would have been contrary to standard manufacturing principles to make a discharge conduit with a ratio of above 6/1 due to undesirable effects on manufacturing operations and machinery (Sund Declaration, ¶¶ 11-12), and (2) since the benefits of the claimed invention of reduced energy needed to make a jet injection would have been surprising to one of ordinary skill in the art prior to the filing of the invention (Sund Declaration, ¶ 13). Consequently, claims 1, 16, 20-22, and 27-29 are neither anticipated nor obvious over the art of record. For these reasons, the claimed ratio of

at least 9/1, as defined in claims 3, 18, 19, and 23, is also not shown or inherent in the Lilley patent description, and there is even less of a case for obvious for these claims. (*See,* Sund Declaration, ¶¶ 10 and 12).

Highlighting embodiments that take advantage of the surprising benefits provided by the invention, claim 24 recites that the steady state pressure produced is less than 4000 p.s.i., and claim 25 further recites that the energy source produces up to around 40 lbs. to inject the fluid. Mr. Sund declares that these parameters are lower than would have been used with lower length to average diameter discharge channels, Lilley does nothing to described or even suggest that using these parameters world work to one of ordinary skill in the art. Claim 26 further defines that the ratio is sufficiently large to jet inject the fluid with a successful injection rate into patients of at least about 98% using these parameters. Mr. Sund also declares that there is no suggestion that a ratio of at least 6/1 would allow obtaining such a high success rate using the parameters of claims 24 and 25. (Sund Declaration, ¶ 14).

Although Applicants still disagree with the obviousness-type double patenting rejection, to expedite the allowance of this application, a terminal disclaimer is being concurrently filed herewith. It is noted that when the current application was filed, it was co-assigned to Medi-Ject Corporation and Becton Dickinson and Company. Co-assignee Medi-Ject Corporation changed its name to Antares Pharma, Inc. This change in name was recorded in the parent application.

All of the claims are now believed to be in condition for allowance. (*See,* Sund Declaration, ¶ 15). Should any issues remain, a personal or telephone interview is respectfully requested to expedite the allowance of the application. No fees are believed to be due for this amendment. Should any fees be required, please charge such fees to Winston & Strawn LLP Deposit Account No. 50-1814.

Respectfully submitted,

2/27/06

Date

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